

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: LEVAQUIN PRODUCTS
LIABILITY LITIGATION

MDL No. 08-1943 (JRT)

This Document Relates to:

Civil No. 08-5743 (JRT)

JOHN SCHEDIN,

Plaintiff,

v.

**MEMORANDUM OPINION AND
ORDER DENYING
DEFENDANT'S MOTION FOR A
RELIEF FROM JUDGMENT**

ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC.,

Defendant.

Ronald S. Goldser and David M. Cialkowski, **ZIMMERMAN REED, PLLP**, 1100 IDS Center, 80 South Eighth Street, Minneapolis, MN 55402; Mikal C. Watts, **WATTS LAW FIRM, LLP**, 555 North Carancahua, Suite 1400, Corpus Christi, TX 78478, and Lewis J. Saul and Kevin M. Fitzgerald, **LEWIS SAUL & ASSOCIATES**, 183 Middle Street, Suite 200, Portland, ME 04101, for plaintiff Schedin.

John D. Winter, **PATTERSON BELKNAP WEBB & TYLER**, 1133 Avenue of the Americas, New York, NY 10036; James B. Irwin, **IRWIN FRITCHIE URQUHART & MOORE, LLC**, 400 Poydras Street, Suite 2700, New Orleans, LA 70130; Tracy J. Van Steenburgh and Dana M. Lenahan, **NILAN JOHNSON LEWIS, PA**, 120 South Sixth Street, Suite 400 Minneapolis, MN 55402; and John Dames and William V. Essig, **DRINKER BIDDLE & REATH LLP**, 191 North Wacker Drive, Suite 3700, Chicago, IL 60606, for defendant.

Plaintiff John Schedin brought claims against defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.¹ for failure to warn about certain risks of using its drug, Levaquin,

¹ Now Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC. (See Pretrial Order 7a, Dec. 29, 2011, Docket No. 282.)

specifically the risk of tendon rupture. His case was the first tried in multi-district litigation involving numerous plaintiffs. The jury found for Schedin and awarded compensatory and punitive damages. The Court denied Defendant's post-trial motions, and Defendant filed a still-pending appeal in the Eighth Circuit Court of Appeals. Defendant now seeks relief from judgment pursuant to Federal Rule of Civil Procedure 60. Defendant contests that Schedin's failure to disclose some calculations of his expert witness, Dr. Martin Wells, entitles them to relief from judgment pursuant to Rule 60(b)(2) and Rule 60(b)(3). The Court will deny Defendant's Rule 60(b)(2) motion because Defendant fails to demonstrate that the evidence is material and not merely cumulative or impeaching or that the evidence is such that a new trial would probably produce a different result. The Court will also deny Defendant's Rule 60(b)(3) motion because Defendant has not shown, by clear and convincing evidence, that Schedin engaged in a fraud or misrepresentation that prevented it from fully and fairly presenting its case.

BACKGROUND

Dr. Wells' Expert Report

On October 13, 2009, Schedin served the Expert Report of Dr. Wells, a biostatistician, in the multi-district litigation. (Aff. of Dana M. Lenahan, Ex. A., Expert Report, Docket No. 286.) The report criticized the validity of the Ingenix study, Defendant's epidemiological study that compared the risk of Achilles tendon rupture with Levaquin and other fluoroquinolones. (*See, e.g., id.* ¶ 4.) Dr. Wells criticized numerous aspects of the study (*e.g., id.* ¶¶ 11-16), and he performed new analyses on the underlying

data. In Paragraph 28, Dr. Wells stated that the Ingenix study's filtering of the data resulted in underreporting of the risks of Levaquin compared to ciprofloxacin, another fluroquinolone, **in the Medicare population.** (*Id.* ¶¶ 28, 31.) In Paragraph 32, Dr. Wells also reported that he found an increased risk of Achilles tendon rupture in the entire population of Levaquin-exposed individuals used as the basis for the Ingenix study. (*Id.* ¶ 32.) Dr. Wells did **not** report the relative risk of Achilles tendon rupture for patients taking ciprofloxacin **in the entire population.** The failure to report this information (the ciprofloxacin odds ratio) and the underlying calculation (the ciprofloxacin calculation) is the basis of each of Defendant's arguments.

Defendant's Requests and Dr. Wells' Testimony

On November 24, 2009, Defendant noticed the deposition of Dr. Wells and requested that he produce “[a]ll data and other information received or reviewed in connection with the formation of your opinions, whether or not you relied on that data or information.” (Lenahan Aff., Ex. B., Dep. Notice.) On December 10, 2009, Defendant took Dr. Wells’ deposition. During this deposition, Defendant did not specifically ask Dr. Wells for the calculation and data underlying paragraph 32. (*See id.* 144:5-146:7.)

Dr. Wells testified during Schedin’s trial (in November 2010) about the flaws of the Ingenix study. He also testified that **in the Medicare population** there was a significant association between Levaquin and Achilles tendon rupture but that the same association was not seen with ciprofloxacin. (Lenahan Aff., Ex. E., Schedin Trial Tr. 582:3-17.) Defendant did not ask, and Dr. Wells did not disclose the comparative risks of Levaquin and ciprofloxacin for **all patients in the dataset.**

In May 2011, Defendant sent a letter requesting the “production of the calculations performed by Martin Wells using the Ingenix data and discussed in Wells’ Expert Report . . .” (Lenahan Aff., Ex. X.) Schedin’s counsel responded by e-mail, “You have all there is. Any calculations that Dr. Wells did were on his computer and there is no record of the calculations.” (Lenahan Aff., Ex. I.)

During the second trial in this multi-district litigation (in June 2011), *Christensen v. Johnson & Johnson*, Defendant again questioned Dr. Wells about paragraph 32 and the underlying calculations. Defendant asked whether Dr. Wells compared the risk of Achilles tendon rupture for patients taking Levaquin with the risk for patients taking ciprofloxacin in the entire population, he testified, “Yeah, I probably did. I probably did.” (Lenahan Aff., Ex. J, Christensen Tr. 761:21-762:13.) When asked where the results of those calculations were, Dr. Wells said they were “probably still in the computer.” (*Id.* 761:15-15.) When asked why the calculation had not been produced, Dr. Wells said that when he did the calculations they printed out on the screen and to record them he wrote them down. (*See id.* 766:7-767:10.) Dr. Wells also noted that the dataset he used to do the calculation was “available” to Defendant. (*Id.* 767:1-4.)

Dr. Wells next testified during the first trial of the New Jersey consolidated Levaquin litigation proceedings (in September 2011). Prior to that trial, Dr. Wells produced some of the Expert Report’s underlying calculations to the New Jersey plaintiff’s counsel. (*See* Lenahan Aff., Ex. K 103:6-15.) In response to questions about the calculations underlying paragraph 32, Dr. Wells testified that even though they were

not in his report he “must have” calculated the risk of Achilles tendon rupture for patients taking ciprofloxacin. (*Id.* 105:6-9.)

Immediately after Dr. Wells’ testimony in the New Jersey trial, Defendant’s counsel sought access to the calculations that Dr. Wells had produced in the New Jersey litigation. (Lenahan Aff., Ex. L.) On October 24, 2011, Schedin’s counsel produced the calculations, but no explanation of the calculations was included. (Lenahan Aff. Ex. M.) On October 25, 2011, Defendant’s counsel asked for an explanation of how the calculations related to Defendant’s May 2010 request. (Lenahan Aff., Ex. N.) Schedin’s counsel responded that “[t]he calculations provided . . . are the calculations you requested” and that Dr. Wells had redone the calculations at the request of New Jersey counsel. (*Id.*) Schedin’s counsel did not explain which calculations produced results referenced in the Expert Report.

On November 25, 2011, Defendant’s counsel again asked Schedin’s counsel to explain the relationship between the calculations produced in the New Jersey trial and the calculations discussed in paragraph 32 of Dr. Wells’ Expert Report. (Lenahan Aff., Ex. O.) Schedin’s counsel responded on December 2, 2011, and provided the odds ratio, that is the risk of Achilles tendon rupture for patients taking ciprofloxacin. (Lenahan Aff., Ex. P.) The risk of Achilles tendon rupture for the entire population of the Ingenix study was higher in patients taking ciprofloxacin than in patients taking Levaquin.² Counsel provided the information, not Dr. Wells. (*See id.*)

² The odds ratio for ciprofloxacin exposure is 1.755 (95% CI: 1.371-2.247). (Lenahan Aff., Ex. P.) The odds ratio for Levaquin exposure is 1.606 (95% CI: 1.086-2.306).

Defendant noticed a second deposition of Dr. Wells on January 3, 2012 and requested that he produce “all documents that constitute, reflect, or relate to the calculations underlying paragraphs 28 and 32” of the Expert Report and all documents that relate to the calculation of the odds ratios for the risk of Achilles Tendon rupture for ciprofloxacin. (Lenahan Aff., Ex. R.) On January 5, 2012, Schedin’s counsel produced the calculations used to create the ciprofloxacin calculation of paragraph 28 only. (See Lenahan Aff., Ex. S.) The deposition took place on January 6, 2012. (Goldster Aff., Ex. 3, Second Dep. of Martin T. Wells.) Dr. Wells testified that he could not remember if he had previously calculated the risk of Achilles tendon rupture for the entire population of the Ingenix study in patients taking ciprofloxacin. (*Id.* 22:17-22.) He further testified that when Defendant had previously asked for the calculation he did not have it (*id.* 58:4-6) but that he had re-done the calculations in early December of 2011 (*id.* 58:15-19). Defendant also requested that Dr. Wells produce the calculations underlying the ciprofloxacin odds ratio provided by Schedin’s counsel on December 2. (*Id.* 10:10-11:20, 13:4-10.) Those calculations were produced on January 9, 2012.

On January 10, 2012, Dr. Wells testified in the third trial in this multi-district litigation, *Straka v. Johnson & Johnson*. (Lenahan Aff., Ex. V, Straka Tr.) During this testimony, Dr. Wells indicated that he had not provided all of the data he had created in December 2009 because he had been advised by Schedin’s counsel that he did not need to do so. (*Id.* 1059:11-1061:2.)

ANALYSIS

I. STANDARD OF REVIEW

Under Rule 60(b) a party can seek relief from judgment for:

(2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b); [or]

(3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party

Fed. R. Civ. P. 60(b).³ “The rule ‘provides for extraordinary relief which may be granted only upon an adequate showing of exceptional circumstances.’” *Jones v. Swanson*, 512 F.3d 1045, 1048 (8th Cir. 2008) (quoting *United States v. Young*, 806 F.2d 805, 806 (8th Cir. 1986)). Defendant seeks relief under both Rule 60(b)(2) and (b)(3).

II. DEFENDANT’S RULE 60(b)(2) MOTION

A. Standard of Review

“Motions under Rule 60(b)(2) on the ground of newly discovered evidence are viewed with disfavor.” *Haigh v. Gelita USA, Inc.*, 632 F.3d 464, 472 (8th Cir. 2011) (quoting *U.S. Xpress Enters., Inc. v. J.B. Hunt Transp., Inc.*, 320 F.3d 809, 815 (8th Cir. 2003)). To prevail on a Rule 60(b)(2) motion Defendant must show that (1) the evidence was discovered after trial; (2) they exercised due diligence in discovering it; (3) the evidence is material and not merely cumulative or impeaching; and (4) the evidence is such that a new trial would probably produce a different result. *Id.* Defendant alleges

³ “A motion . . . must be made within a reasonable time – and for reasons . . . (2), and (3) no more than a year after the entry of the judgment or order or the date of the proceeding.” Fed. R. Civ. P. 60(c). The motion was timely made.

that the ciprofloxacin odds ratio and the ciprofloxacin calculation are newly discovered evidence that meets the standards of Rule 60(b)(6).

B. Due Diligence

First, Defendant must demonstrate that they exercised due diligence in discovering the new evidence. *Id.* To demonstrate “due diligence,” Defendant must offer a “‘justifiable excuse’ for not discovering the material in a timely manner.” *Scott v. Apfel*, 194 F.R.D. 655, 658 (N.D. Iowa 2000) (citing *Alpern v. UtiliCorp United, Inc.*, 84 F.3d 1525, 1537 (8th Cir. 1996)). Defendant claims they could not perform the same analysis required to calculate the ciprofloxacin odds ratio because they did not know Dr. Wells’ methodology. Although the Court is not convinced that Defendant was unable to recreate this calculation before trial,⁴ it will assume for the purposes of this motion that Defendant exercised due diligence.

C. Cumulative or Impeaching

Defendant must also establish that “the evidence is material and not merely cumulative or impeaching[.]” *Haigh*, 632 F.3d at 472. Both the ciprofloxacin odds ratio and the fact that Dr. Wells had performed the underlying calculation could be used for impeachment. But Defendant argues that the calculation had broader implications because Dr. Wells’ testimony at trial “went to the substantive issue of whether the risk of

⁴ Defendant suggested at oral argument that the Court should not deny the motion simply because the evidence was available through another avenue. Defendant offered no support for this proposition. *Cf. Baxter Int’l, Inc. v. Morris*, 11 F.3d 90, 93 (8th Cir. 1993) (“The court also pointed out that [Plaintiff] had other avenues to discover the [evidence]. We agree.”); *Pri-har v. United States*, 83 F. Supp. 2d 393, 401 (S.D.N.Y 2000) (“Expert reports . . . based upon evidence available to the defense at trial[] do not constitute new evidence.”).

[Achilles tendon rupture] is greater with Levaquin® than other fluoroquinolones including ciprofloxacin.” (Def.’s Mem. in Supp. at 25, Mar. 5, 2012, Docket No. 285).

While the ciprofloxacin odds ratio might have provided Defendant with slightly more support for their case, the Court finds that the evidence is cumulative. Defendant offered other expert testimony that Levaquin is no more tendon toxic than other fluoroquinolones. *Cf. Rosebud Sioux Tribe v. A & P Steel, Inc.*, 733 F.2d 509, 516 (8th Cir. 1984) (finding the newly discovered evidence was not cumulative when it was the only “concrete” – not circumstantial – evidence). Defendant also offered evidence at trial that the methodology of the Ingenix study was sound. The Court therefore concludes that the evidence was merely cumulative or impeaching.

D. Different Result

Even if Defendant exercised due diligence and the evidence was material, Defendant must also show that the evidence “is such that a new trial would probably produce a different result.” *Haigh*, 632 F.3d at 472. Defendant asks the Court to assume that Dr. Wells’ testimony was key to the case,⁵ but the Court is not convinced. Even if Dr. Wells was a critical witness, his criticisms of the Ingenix study were broad and would not be wholly undermined by the ciprofloxacin calculation.⁶ Moreover, “admission of

⁵ Defendant argues that Dr. Wells’ testimony regarding the flaws of the Ingenix study was critical to Schedin’s case, that Dr. Wells’ ciprofloxacin calculation would have demonstrated to the jury that the Ingenix study did not skew the results, and that the evidence would have cast doubt on Schedin’s comparative toxicity theory.

⁶ For example, Dr. Wells suggested that the Ingenix study underreported the risks of Levaquin in the Medicare population. Data demonstrating that Levaquin was not more dangerous than other fluoroquinolones in the study’s **total** population does not contradict Dr. Wells’ conclusion that the study underrepresented the drug’s risks in some sub-populations.

the evidence would not produce a different result because liability rested not only on [Dr. Wells'] testimony, but on the record as a whole.” *Greyhound Lines, Inc. v. Wade*, 485 F.3d 1032, 1037 (8th Cir. 2007).

Defendant tries to draw parallels to *Rosebud Sioux Tribe*, but unlike that case, “the entire complexion of the case” has not changed. 733 F.2d at 516. The ciprofloxacin calculation does not “contradict any testimony at trial.” *Baxter Int’l, Inc. v. Morris*, 11 F.3d 90, 93 (8th Cir. 1993) (distinguishing *Rosebud Sioux Tribe*). In sum, the Court will deny Defendant’s Rule 60(b)(2) motion because the newly discovered evidence was merely cumulative or impeaching and Defendant has not demonstrated that it was probable it would produce a different result.

III. DEFENDANT’S RULE 60(b)(3) MOTION

A. Standard of Review

To prevail on a Rule 60(b)(3) motion, Defendant must show, by clear and convincing evidence, that the opposing party engaged in a fraud or misrepresentation that prevented them from fully and fairly presenting their case.⁷ *United States v. Metro. St. Louis Sewer Dist.*, 440 F.3d 930, 935 (8th Cir. 2006). It is within the Court’s discretion to determine “whether the Rule 60(b)(3) test has been met . . .” *Id.*

B. Misconduct, Fraud, or Misrepresentation

Defendant argues that Schedin’s attorneys withheld expert discovery materials and so have engaged in misconduct under Rule 60(b)(3). Even assuming that withholding

⁷ Defendant suggests that the Rule 60(b)(3) standard is more lenient than the Rule 60(b)(2) standard. It provides no Eighth Circuit authority to support this proposition.

expert discovery can be misconduct under Rule 60(b)(3),⁸ the Court finds that there was no violation of the Rule.

Dr. Wells testified that he did his calculations on a computer program that did not retain the results unless he saved or printed them. (*See Second Wells Dep.* 10:6-9, 12:5-9, 12:25-13:2.) Dr. Wells did not recall doing the calculation for the ciprofloxacin odds ratio, and if he did, apparently did not save it because he had to recreate it before it was eventually produced. If Schedin's attorneys, in fact, advised Dr. Wells that he did not have to produce a calculation that he did not remember doing and of which he had no record, they were not withholding discovery materials. *See Helmert v. Butterball, LLC*, No. 4:08CV00342, 2011 WL 3157180, at *2 (E.D. Ark. July 27, 2011) (holding that while the opposing party was entitled to the underlying data used by an expert, the expert did not have to produce all of his notes and calculations); *Flebotte v. Dow Jones & Co.*, No. Civ.A. 97-30117, 2000 WL 35539238, at *7 (D. Mass. Dec. 6, 2000) ("Therefore, neither the plain language of [Rule 26] nor its purpose compels disclosure of every calculation or test conducted by the expert during formation of the report.").

Defendant argues that the failure to produce the calculations was particularly egregious in light of the Court's other pretrial orders. The Court did conclude that another expert witness should have disclosed her consideration of a database analysis and produced that underlying data. (MDL Docket No. 2277 at 5-6.) In contrast, Dr. Wells

⁸ Other circuits have held that withholding discovery from an opposing party constitutes misconduct under Rule 60(b)(3). *See, e.g., Abrahamsen v. Trans-State Express, Inc.*, 92 F.3d 425, 428 (6th Cir. 1996); *Anderson v. Cryovac, Inc.*, 862 F.2d 910, 923 (1st Cir. 1988). *See also Rauenhorst v. United States*, 104 F.R.D. 588, 598 (D. Minn. 1985) (Rule 60(b)(3) may be properly applied to misconduct in withholding information called for by discovery).

disclosed what data he used and that data was available to both parties – he not only used data from Defendant's Ingenix study but the calculation that Defendant claims was not disclosed was performed on an identified subset. The Court concludes that Defendant failed to demonstrate that Schedin's attorneys or Dr. Wells engaged in misconduct sufficient to support application of Rule 60(b)(3).

C. Defendant's Inability to Fairly Present Their Case

Defendant also contends that the lack of the ciprofloxacin odds ratio data prevented them from fairly presenting their case. The Court finds that the lack of the calculation did not prevent Defendant from mounting a vigorous (and in the case of *Christensen* wholly successful) defense. While Defendant might have been inconvenienced, any misconduct does not warrant a new trial. The Court will, therefore, deny Defendant's Rule 60(b)(3) motion because Defendant has not shown that the opposing party engaged in a fraud or misrepresentation that prevented them from fully and fairly presenting their case.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Janssen Pharmaceuticals, Inc.'s Motion for Relief from Judgment Pursuant to Rule 60(b) [Docket No. 283] is **DENIED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

DATED: August 17, 2012
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge